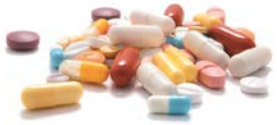


EXPERT
SANTÉ CANADA
MAPAQ

Agriculture, Pêcheries et Alimentation
Québec

HACCP Certification
ISO22000
GFSI
SQF

PBE-Expert Inc – CANADA

Accredited training organisation CPMT #0059104

Qualified MAPAQ Consultant

To the measure 2 of the Levier program

PBE, Accredited Training Organisation **CPMT** #0059104

Agriculture, Pêcheries et Alimentation Québec

Commission des partenaires du marché du travail Québec

CERTIFICAT D'AGRÉMENT

Loi favorisant le développement et la reconnaissance des compétences de la main-d'oeuvre

Titulaire : PBE, PHARMA BIO EXPERT INC.

Numéro d'agrément : 0059104

NEQ : 1168916956

Catégorie d'agrément : Organisme formateur

Date de délivrance : 6 février 2018

Date d'échéance : 5 février 2020

CHAMPS PROFESSIONNELS

01 Administration et commerce
03 Alimentation, hôtellerie et tourisme
06 Chimie et biologie

Par : Isabelle Bergeur

Le 7 février 2018

La délivrance du certificat est valide en fonction des documents soumis à la Commission des partenaires du marché du travail.

Ministère du Travail, de l'Emploi et de la Solidarité sociale

EQ-6282 (06-2003)
ENT-0031 (12-2016)

PBE PharmaBio EXPERT cGMP

EXPERT SANTÉ CANADA MAPAQ

PBE EXPERT

PBE, Qualified MAPAQ Consultant at the measure 2 of the Levier program

Agriculture, Pêcheries et Alimentation Québec

From: De Meyer Emmanuelle (DDEP) (Québec) [mailto:Emmanuelle.DeMeyer@mapaq.gouv.qc.ca]
Sent: Thursday, January 25, 2018 12:21 PM
To: Aziz.pbe <aziz.chraibi@pharmabioeng.com>
Subject: RE: PBE, Pharma Bio Expert Santé Canada

Agriculture, Pêcheries et Alimentation Québec

Bonjour Monsieur Chraibi,

Simplement pour vous informer qu'après évaluation, votre candidature a été intégrée à la *Liste des consultants qualifiés à la mesure 2 du programme Levier*.

Vous recevrez une lettre officielle dans les prochaines semaines, mais ne vous inquiétez pas si elle tarde. Dans l'éventualité où vous auriez des clients en attente de votre acceptation, ce courriel peut faire foi de votre qualification.

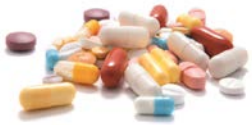
Si vous avez des questions, surtout n'hésitez pas à communiquer avec moi.

Je vous souhaite une belle journée,

Emmanuelle De Meyer B. Sc. A | Conseillère en transformation alimentaire
Direction du développement des entreprises et des produits
Ministère de l'Agriculture, des Pêcheries et de l'Alimentation

200, chemin Sainte-Foy, 12e étage
Québec (Québec) G1R 4X6
Téléphone : 418 380-2100, poste 3795
Télécopieur : 418 380-2134
Emmanuelle.DeMeyer@mapaq.gouv.qc.ca
www.mapaq.gouv.qc.ca

PBE PharmaBio cGMP EXPERT



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Training goals

Agriculture, Pêcheries et Alimentation Québec

1. Framework & Regulatory Requirements
2. Types of bottling water, definitions & characteristics
3. General requirements for water bottling units
4. Production units, packaging & labeling Audit
5. CIP performance: Cleaning, Disinfection & Hygiene
6. Production, Cleaning & Sanitization Units
7. Critical premises compliance & contaminants types
8. Dress code & Prevention
9. Room classification vs Standards & Applications
10. Architechtural Building Elements and Finishes
11. URS / CDC Respect (to be revisited).
12. Segregation (Phy/Mec), Flow & Cascades Types.
13. HVAC systems design.
14. Audit & Inspection & Remediation Plan & Upgrade.

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FRAMEWORK & REGULATORY REQUIREMENTS

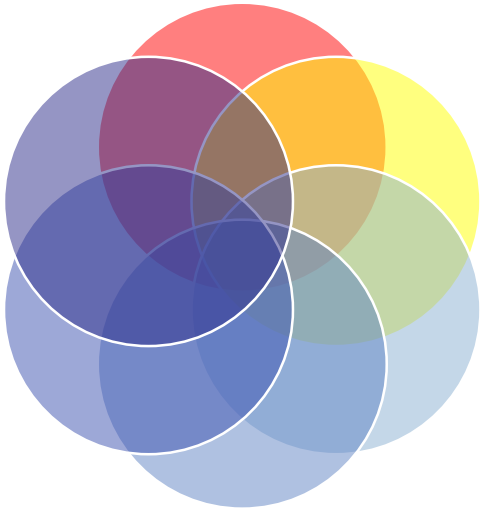
Regulatory References ?

Agriculture, Pêcheries et Alimentation Québec

URS / CDC

ONTH

ISO 17025



Tunisian standards

NT09-33, NTO09-33

NT09-83, NT15-23

ISO 14644 ?

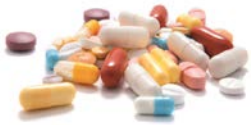
ISO 22000 ?

HACCP

CODEX

Decree **N°68-328**

October 20, 1968



HACCP Definitions & Actions

Agriculture, Pêcheries et Alimentation Québec

HACCP = « Hazard Analysis Critical Control Point »
or hazard analysis at critical points for control.

HAZARD =

- biological agent,
- chemical agent,
- physical agent,
- or condition of the food with potentially harmful effect on health.

RISK =

- Product of the occurrence **probability** of the event and of its **gravity**.
- The **estimate** is based on the hazard **identifiability**, the extent of its **effects** and the extent of its **exposure** to danger.

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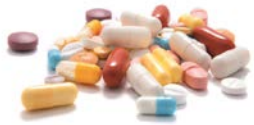

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HACCP Definitions & Actions

Agriculture, Pêcheries et Alimentation Québec

CCP or « Critical Control Point » =

- Characteristical product point, step or process whose **mastery** is **critical** and possible to efficiently prevent, reduce or eliminate a hazard of high impact on product security.

CORRECTIVE ACTION =

- All action to be taken when **results** of a critical point **monitoring** indicate a **loss of control**.

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HACCP Definitions & Actions

(According to CE 178/2002, 852/2004, 853/2004 Regulations)

Agriculture, Pêcheries et Alimentation Québec

CONTROL ACTION = (ex Preventives Actions)

- Any intervention or activity that may be **used to prevent** or **eliminate a hazard** that threatens the safety of a food or to reduce it to an **acceptable level**.

CRITICAL THRESHOLD =

- **Criterion** distinguishing **acceptability** from non-acceptability.

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HACCP Definitions & Actions

(Selon Règlement CE 178/2002, 852/2004, 853/2004)

Agriculture, Pêcheries et Alimentation Québec

HACCP = A system that :

- **identifies**,
- **évaluate**,
- **masters** significative hazards,
- considers **food safety**
- is based on **7 principles**

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General Requirements of a 7 Points HACCP Plan

General requirements of a 7 points HACCP Plan

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1. ☞ Hazard analysis
2. ☞ Determine CCP or Critical Control Points
3. ☞ Establish crital limits for each CCP
4. ☞ Establish a monitoring system for each CCP
5. ☞ Establish corrective actions
6. ☞ Establish verification procedures
7. ☞ Establish a documentation recording system.

Logic Application Sequence of 1-5 HACCP system

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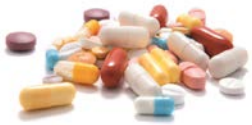
1- Establish the HACCP team

2- Describe the product

3- Determine its intended use

4- Establish a process flow chart

5- Check the process flow chart on site



Logic Application Sequence of 6-9 HACCP system

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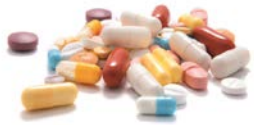
6- List all potential hazards / Perform a risk analysis / Consider control actions

7- Determine the CCP

8- Set a critical threshold for each CPP

9- Implement a monitoring system for each CPP



Logic Application Sequence of 10-12 HACCP system

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10- Take corrective actions

11- Apply verifications procedures

12- Keep and build records

ISO 22000

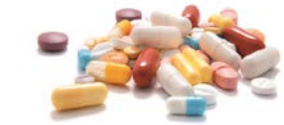
Agriculture, Pêcheries et Alimentation Québec

ISO/TS 22002-3: 2011

ISO 22000:2005 - Food safety management systems — Requirements for any organization in the food chain

ISO 22000:2005

ISO 22000



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ISO 22000

Agriculture, Pêcheries et Alimentation Québec

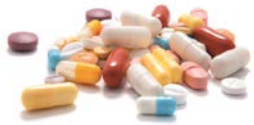
ISO/TS 220003:2007 - Food safety management systems — Requirements for bodies providing audit and certification of food safety management systems

S 22002-3: 2011

ISO /TS 22003:2007

ISO 22000:2005

ISO 22000



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ISO 22000

Agriculture, Pêcheries et Alimentation Québec

ISO/TS 22002-1:2009 - Prerequisite programs on food safety — Part 1: Food manufacturing

ISO/TS 22002-3: 2011

ISO/TS 22002-1:2009

ISO /TS 22003:2007

ISO 22000:2005

ISO 22000

ISO 22002 describes the basic conditions and activities necessary to maintain an adequate hygienic environment for the production, handling and delivery of safe finished products.

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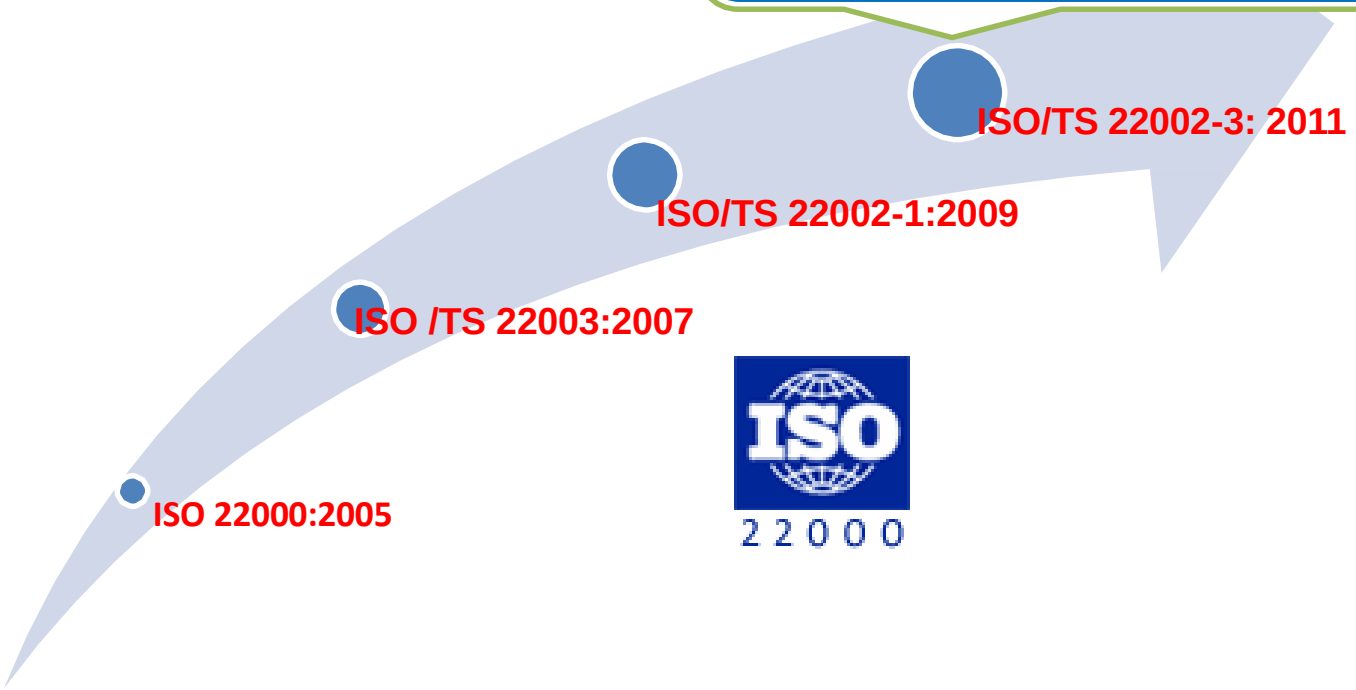
ISO 22000

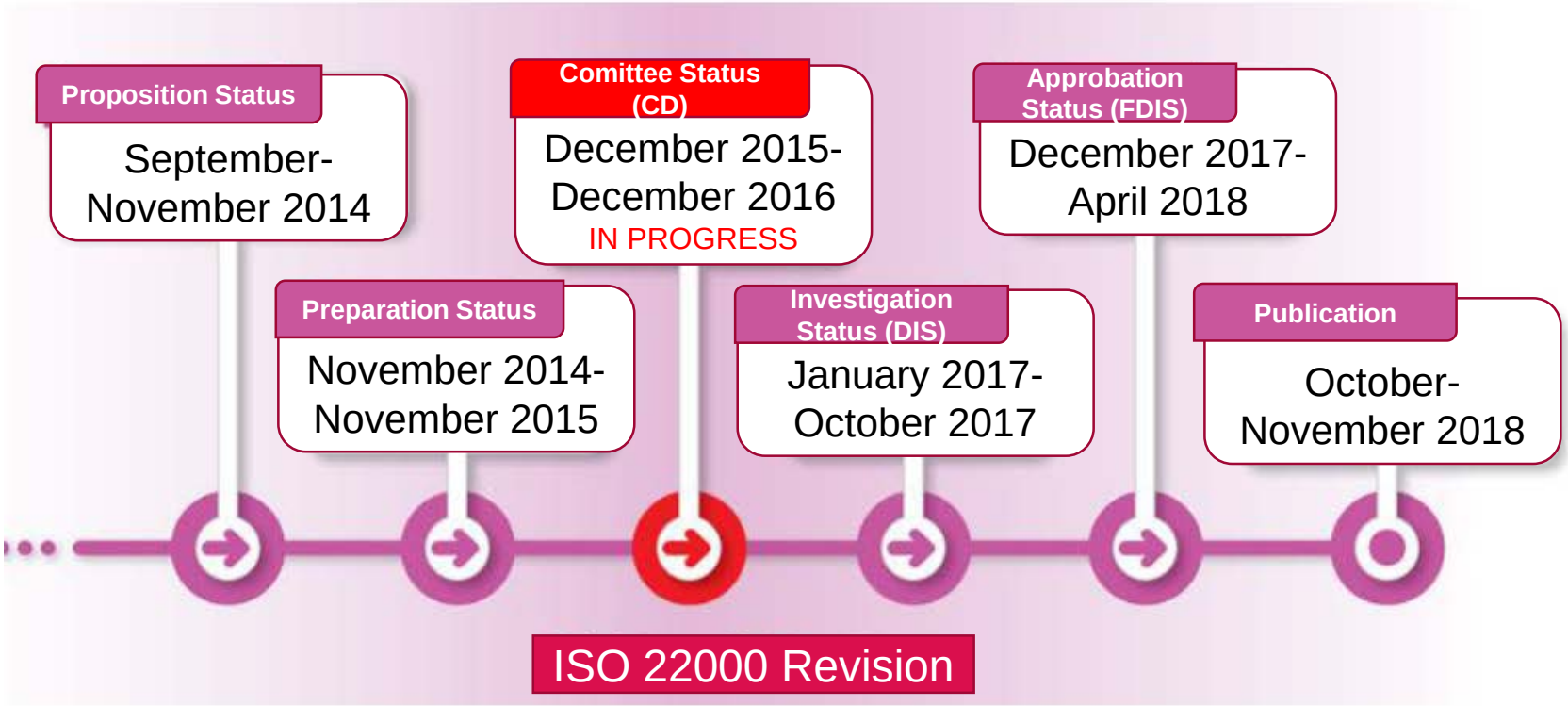
Agriculture, Pêcheries et Alimentation Québec

ISO/TS 22002-3:2011 - Prerequisite programs on food safety — Part 3: Farming



ISO 22000 Revision (2015)

Agriculture, Pêcheries et Alimentation Québec



Goal: clarification of keys concepts, definitions, terminology and simplification

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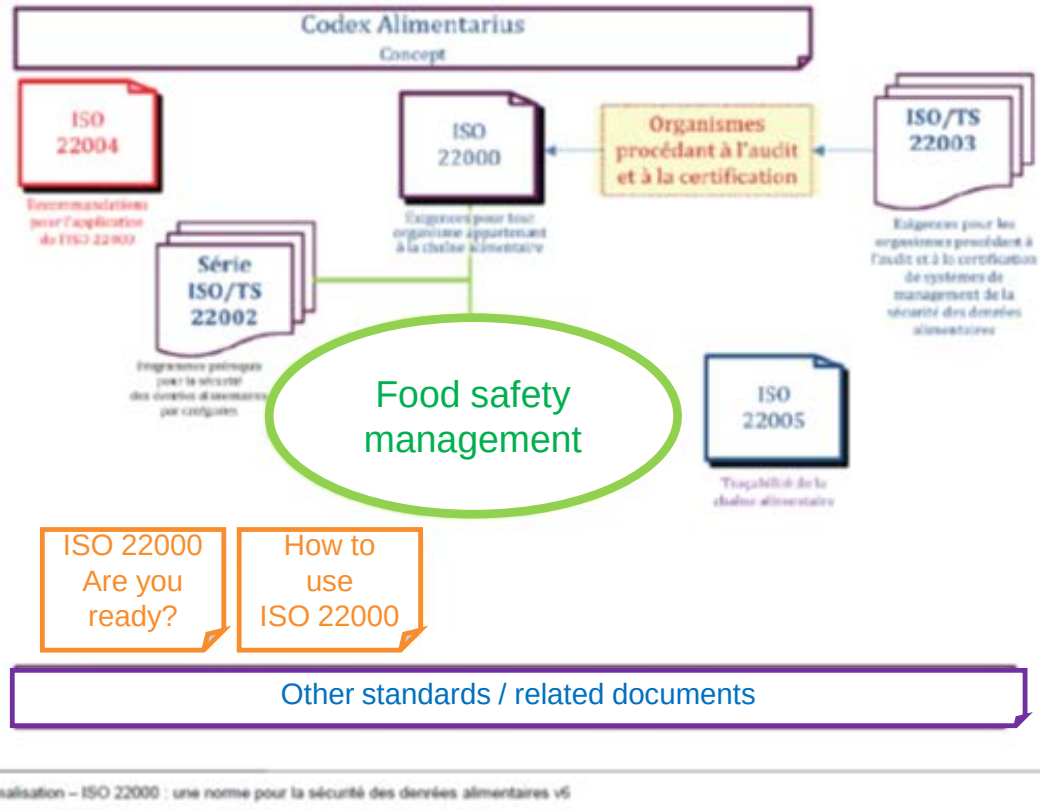
All documents related to ISO 22000

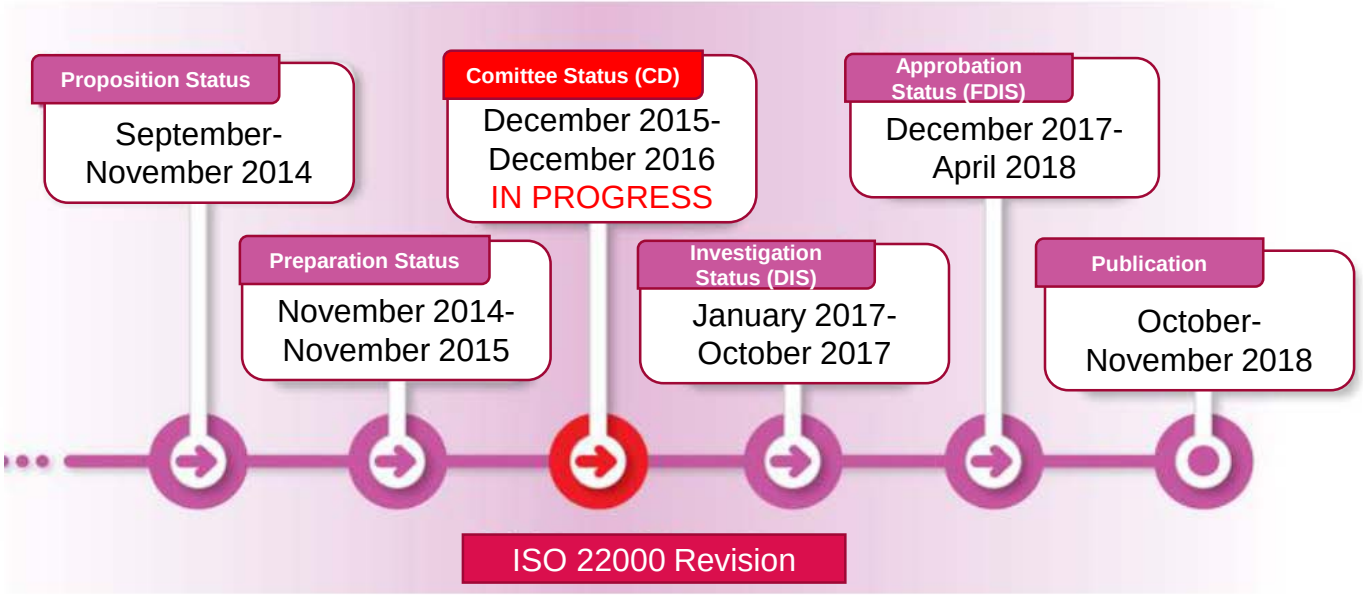
Agriculture, Pêcheries et Alimentation Québec



AFNOR Normalisation – ISO 22000 : une norme pour la sécurité des denrées alimentaires v6 Page 15

ISO 22000 Revision

Agriculture, Pêcheries et Alimentation Québec



The revision of the standard is conducted by experts from more than 35 countries, specialized in the establishment, implementation and audit of food safety management systems (ISO/TC 34/SC 17/WG 8).

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ISO 22000

www.mygfsi.com

Agriculture, Pêcheries et Alimentation Québec

Hazard•Analysis HACCP Critical•Control•Point

GFSI Global Food Safety Initiative

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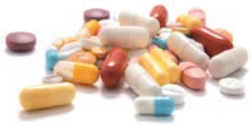

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1

How do we meet the basic requirements for food safety?

2

Where are we in relation to the safety of our products?

3

What are the goals in food safety?

4

How to plan our food safety management system?

5

Which method to effectively implement our management system?

6

What do we do in case of an accident?

7

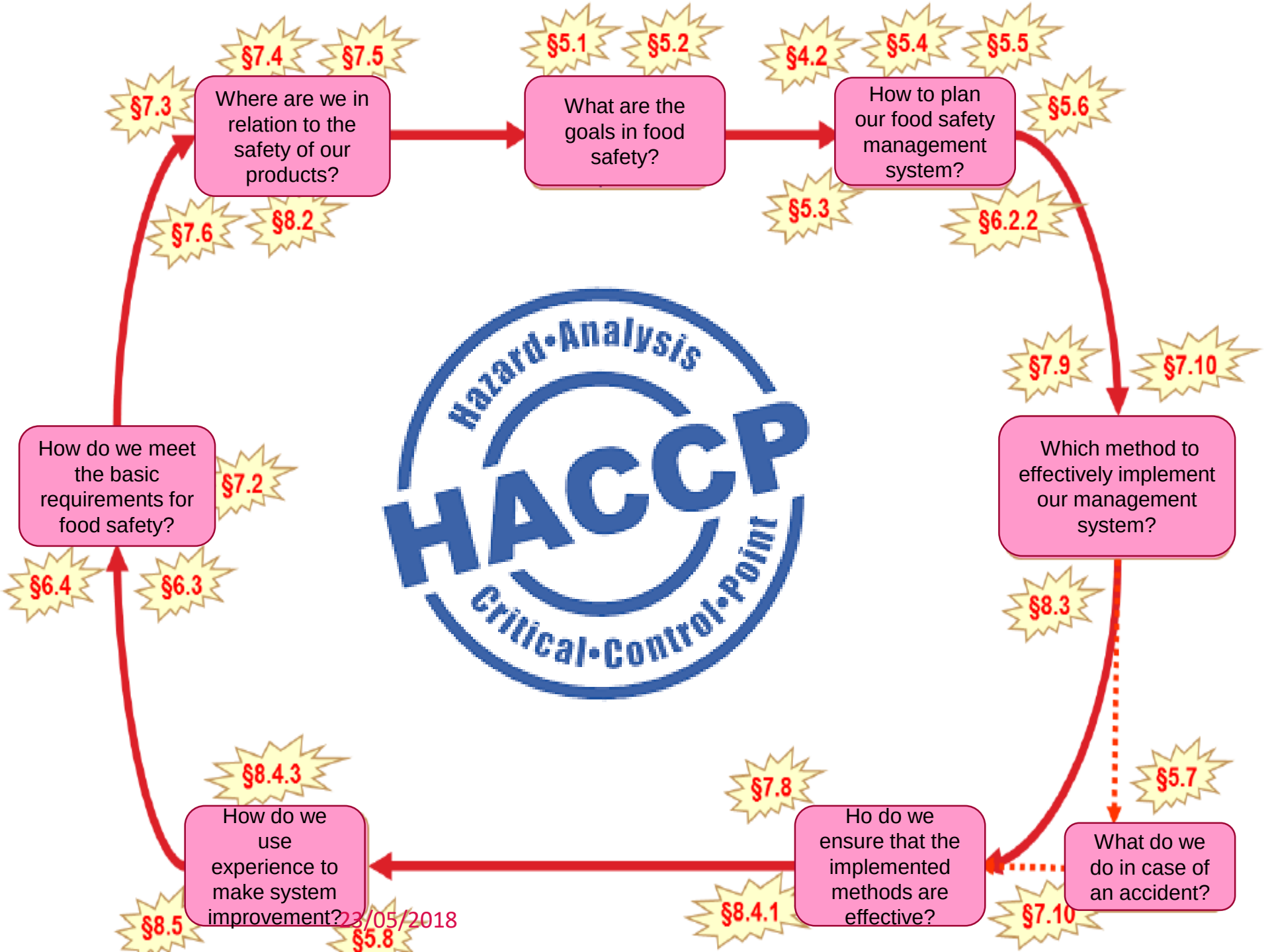
Ho do we ensure that the implemented methods are effective?

8

How do we use experience to make system improvement?

ISO 22000 System

Continuous improvement consist of making stadium rounds by completing each steps.


§7.4
§7.5
§7.3
Where are we in relation to the safety of our products?
§7.6
§8.2
§5.1
§5.2
What are the goals in food safety?
§4.2
§5.4
§5.5
§5.6
How to plan our food safety management system?
§5.3
§6.2.2
§7.9
§7.10
Which method to effectively implement our management system?
§8.3
§5.7
What do we do in case of an accident?
§7.10
§7.8
Ho do we ensure that the implemented methods are effective?
§8.4.1
§8.4.3
How do we use experience to make system improvement?
§8.5
§5.8
§7.2
How do we meet the basic requirements for food safety?
§6.4
§6.3
Hazard Analysis
HACCP
Critical Control Point

7.5 Operational Prequisite Programs establishment (operational PRP) ISO-22000 (2005)

Agriculture, Pêcheries et Alimentation Québec

OPRP to Document

a) **security hazards** … ;

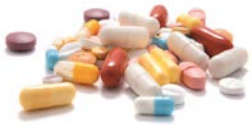
b) **measures ...** ;

c) **procedures ...** ;

d) **corrections and actions ....** ;

e) **responsibilities** …. ;

f) **monitoring**.



&14-18, 56-65 COMPLIANCE AUDIT : FROM PRODUCTION TO PACKAGING AND LABELING UNITS

&14-18, 56-65 – PRODUCTION, PACKAGING AND LABELING COMPLIANCE AUDIT

- Reduce contamination risks from a product to another or by external and internal contaminants ;

- They also insist on hygiene and organisation practice to be implemented.

WATER BOTTLING UNIT

SANITARY PRODUCTION UNIT

&42- PROCEDURES AND TRAINING

&14- « FOOD GRADE » MATERIALS AND EQUIPMENTS

&27- EFFLUENT EVACUATION SYSTEMS

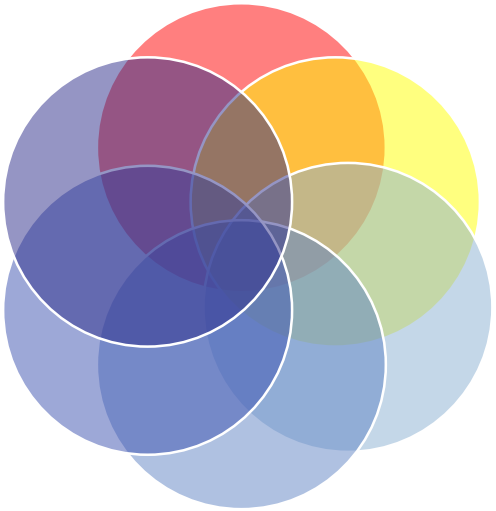
&18, 29- COMPATIBLE WITH CLEANING AND DISINFECTION AGENTS

&53-59 PACKAGING MATERIALS CONFORMING TO CDC

WATER BOTTLING UNIT

FILLING / BOTTLING

VACUUM OR MODIFIED ATMOSPHERE PACKAGING



QUICK COOLING HEAT TREATMENT

CHEMICAL PRESERVATION

AC IRRADIATION & UV

DRYING

Pharmaceutical reference regulation

- International reference: WHO & ICH
- European reference: GMP-EU
- USA reference: cGMP & FDA-Guidance

- Five fundamental GMP characteristics for the product

- Identity
- Security
- Purity
- Efficiency
- Quality

Chronology

A globalized notion

2005: Q9. Quality Risk Management

2005: GMP-Eu Vol 4 Part II: Process criticality analysis (active substances)

2004: Risk Management Guidelines based on cGMP

2003: WHO_TRS_90B. Transposition of HACCP to the pharmaceutical field

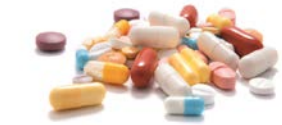
2001: 15 GMP-EU annex. Process criticality analysis, validation and change

2000: ICH/Q7A. Process criticality analysis (active substances)

1998-2002 FDA Software Guidance about information systems

&14-18, 56-65 - PRODUCTION, PACKAGING AND LABELING COMPLIANCE AUDIT

- ....
- ...



Risk analysis origin?

&19-21, 29, 33-38 CIP CLEANING, DISINFECTION & HYGIENE

Non-Compliance & CCP Sources

1-

Sanitary Materials

2-

Material Finishes

3-

Equipment Design

Compressed Air,

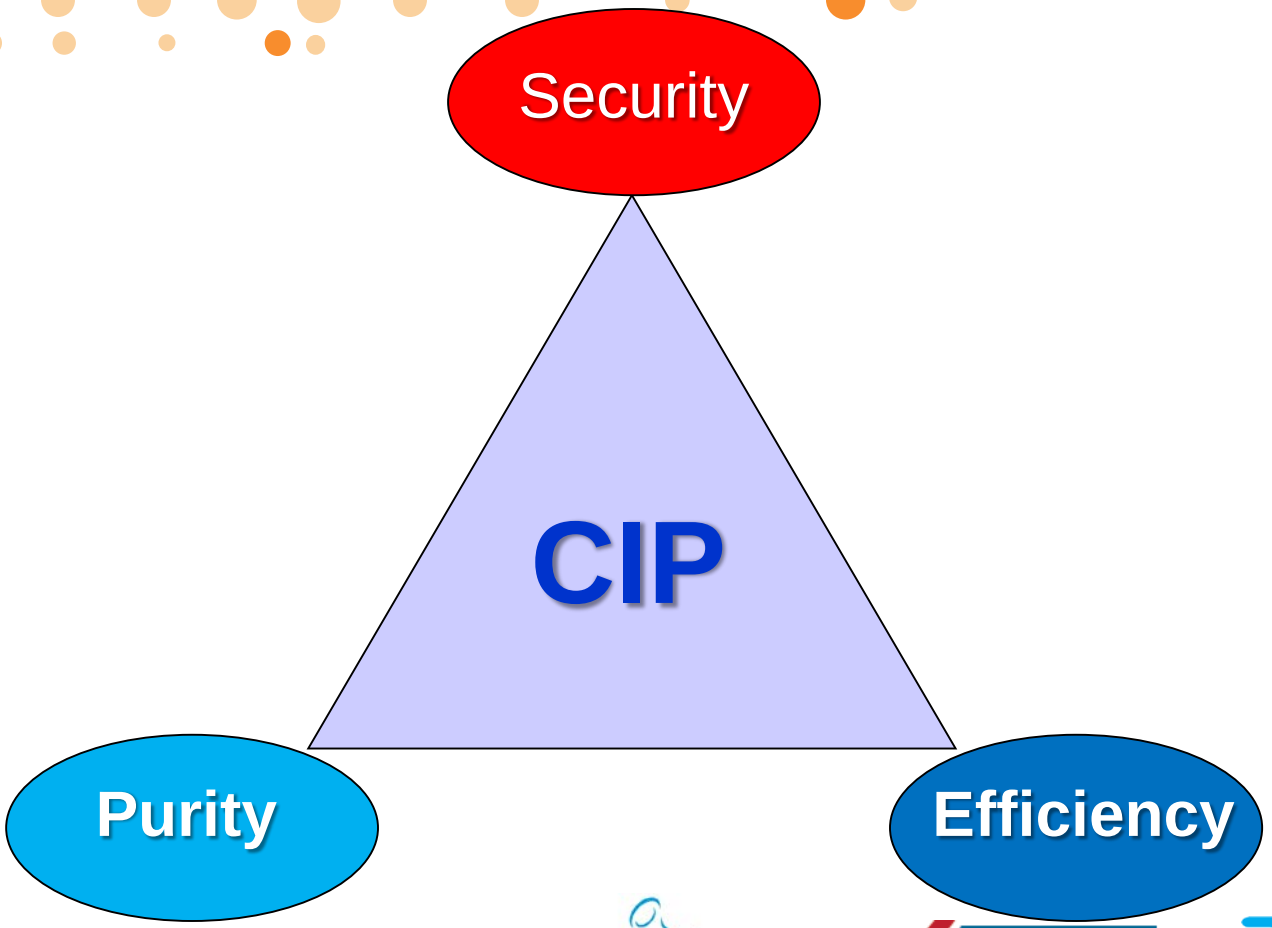
CIP,

Process…

Non-compliance & CCP Sources
CIP & MAINTENANCE

1. Equipment **cleaning and maintenance,** including utensils, must be done according to **....**
2. Cleaning procedures are **...**

Cleaning processes development



4. How a CIP works?

Energy source

Time

Mechanical

Temperature

Chemical

Non-compliance & CCP Sources
CIP & MAINTENANCE

1. ….
2. …
3. ...
4. ..
5. .

&19-25, 33-36, 39 PRODUCTION ROOMS COMPLIANCE AUDIT

&37-54
CONTAMINANTS ORIGINS & HYGIENE RIGOR

&19-25, 33-36 PREVENTIVE TECHNOLOGIES AGAINST CONTAMINANTS

&19-25, 33-36
DRESSING CODE

&19-25, 33-36 HYGIENIC ROOM & PRODUCTION ROOMS CLASSIFICATION / ZAC (ISO-14644)

&19-25, 33-36

LOCAUX HYGIÉNIQUES

FINIS Architecturaux des ZAC

&1-79
Respect des URS / CDC

&19-25, 33-36 BARRIÈRES PHYSIQUES & MÉCANIQUES

&19-25, 33-36 CONCEPTION DES COMPOSANTES CRITIQUES DU SYSTÈME HVAC

PREVENTIVE & SYSTEMATIC MAINTENANCE MONITORING

&68-69 CHEMICAL MICROBIOLOGICAL CONTROL LABORATORY

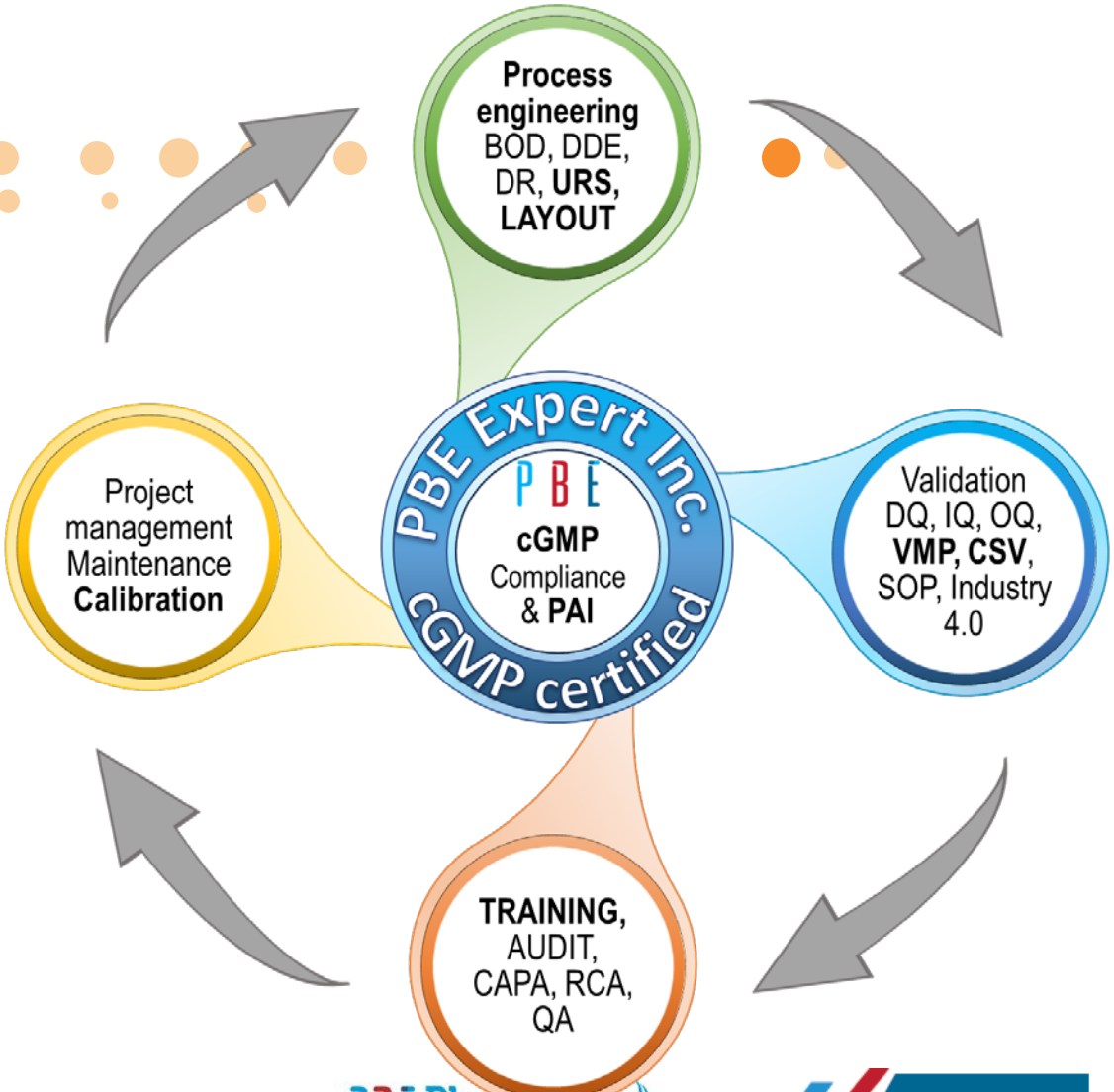
STORAGE
& SUPPLY CHAIN

PROCEDURES APPLICATION

PROCEDURES APPLICATIONS

&67- MANAGEMENT & QUALITY ASSURANCE

&66, 69-79 PERIODIC INSPECTION AUDIT



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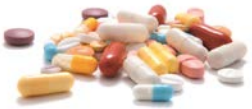
PBE Expert Inc. we Process, Build, Engineer



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